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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,184	12/31/2003	Richard L. Franklin	ARC-1001USCON1	4994

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,184	FRANKLIN, RICHARD L.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *142-153 and 157-164* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *142-153 and 157-164* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

1. Claims 142-153, and 157-164 are pending in the application.

Election/Restrictions

2. Applicant's election with traverse of Group I, wherein the composition comprises a combination of enzymes having the activity of both a trypsin and an exo-peptidase, and wherein the enzymes are isolated from krill of the genus Euphausia in the reply filed on September 6, 2006 is acknowledged. The traversal is on the ground(s) that all the claims of Group II now depend from the independent claim of Group I, and that there would be no undue burden in the examination of each of the claimed species because the claims as amended requires that the multifunctional enzyme is part of a mixture of enzymes. This is found persuasive.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the present application does not share an inventor with prior applications 08/338,501 or PCT/SE93/00455. As the present application does share at least one named inventor with the prior applications, the present application is not entitled to priority to those applications.

It is noted that an Oath or Declaration naming inventors identified in these references was submitted with the application. However, that Declaration was a copy of one submitted as part of a parent application to which priority was claimed as a continuation-in-part, and as such was not

an acceptable declaration for the present application. A later Declaration was submitted on October 15, 2004, which names only one inventor, Richard L. Franklin.

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Sweden on May 22, 2992. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. In the present case, the earliest US application to which the present application is entitled priority benefit was filed on June 7, 1995, which is over 12 months from the filing date of the foreign application. The present application is therefore not entitled to priority from that application for at least this reason.

Information Disclosure Statement

5. The information disclosure statement filed September 6, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed Those references which have not been provided in the English language, and for which no English translation was found in the patent files have not been considered. Also, those references which were deemed not to meet the requirements of 37 CFR 1.97 and 1.98 in the parent application have not been considered.

Specification

6. The disclosure is objected to because of the following informalities:

Pages 2 and 36 (table 2) of the specification appears to include handwritten amendments to the text that are not in conformance with the requirements of 37 CFR 1.121.

The amendment of July 1, 2004 has cancelled the first paragraph of page 1 of the application, and to replace it with a provided paragraph. It is noted that there is no paragraph on page 1 of the application. Thus, it is not clear what paragraph is to be deleted.

The statement of inventorship on page 1 of the application does not match that of the Declaration. Applicant is requested to either provide a new declaration, or to amend the specification to conform with the declaration.

Appropriate correction is required.

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is requested to return a copy of the attached Notice to Comply with the reply.

8. The specification is objected to for containing referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See, pages 2 (lines 18-19, 23, and 26), 36, 43, 45, and claim 157. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d). It is noted that, while sequence identifier numbers have been provided for certain of the disclosed sequences, there is no sequence listing setting forth those sequence identification numbers such that they meet the requirements of the sequence rules.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 142-148, 150-153, 157-164 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindblom et al. (WO 93/24142- of record in the September 2006 IDS) . These claims are drawn to a method of removing dental plaque in mammals comprising contacting the plaque with a hydrolytic enzyme composition comprising a mixture of enzymes isolated from Antarctic krill. Claims 143, 144, 146, and 147 require that the mixture comprising at least two endo-pepsidase and an exo-pepsidase activity. Claims 145 and 150 require that the enzymes have

a molecular weight between 20 and 40 kd. Claims 148 and 164 require that the enzymes are from a member of the genus Euphausia. Claims 151—153, 157, and 158 require that the mixture includes a multifunctional enzyme. Claims 159-161 require that there are at least 6 enzyme in the mixture.

It is noted that the present application (pages 43-47) indicates that among the mixture of enzymes isolated from Antarctic Krill is a multifunctional enzyme meeting the limitations of claims 151-153, 157, and 158.

Lindblom teaches a method for the treatment of plaque in mammals through the administration to the plaque with a composition comprising a mixture of Krill enzymes. Pages 19 and 20. The reference particularly indicates that the enzyme mixture is from a species from the genus of Euphausia, and indicates that the mixture meets the molecular weight limitations of the present claims and that it includes a multifunctional enzyme. Page 4. Because the reference teaches the use of multifunctional enzyme from krill, and the present application indicates that the limitations of claims 151-153, 157, and 158 are inherent to such an enzyme, the limitations of these claims are inherently met by the teachings of the reference. The reference also teaches that the enzyme mixture is mixed with saline, which results in a mixture that may be (and is in the reference) applied topically. Pages 19-20. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 149 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lindblom (supra.). This claim is directed to embodiments of the method of claim 142 (described above) wherein the composition has a purity of at least about 95% with respect to macromolecules. It is noted that the reference teaches the claimed methods except that the reference does not teach the level of purity of the enzyme composition. However, as the reference teaches the use of the purified enzymes, and indicates that methods for isolating and purifying the enzymes from krill were known (page 4), it would have been obvious to those of ordinary skill in the art to optimize the enzyme compositions for use through increased purification of the enzymes. Thus, even if the reference does not teach the claimed invention, the claimed method would have been obvious to those of ordinary skill in the art from those teachings.

13. Claims 142-150, and 159-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (U.S. Patent 4,837,009), in view of Hellgren (U.S. Patent 4,963,491- of record in the IDS of September 2006) and Karlstam (EP 0257003). Each of Ratcliff and Karlstam were cited in the parent application. Copies of these references are therefore not provided. The claims have been described above.

Ratcliff teaches a composition for the reduction, prevention, and treatment of oral diseases involving plaque. The reference teaches that glycoproteins play an important part in bacterial agglutination in the mouth. Col. 3, lines 30-47. The patent further teaches that bacterial

agglutination comprises a complex matrix of glucosamineglycans, proteoglycans, glycoproteins, sugar, proteins, and lipids. Col. 3, line 62-col. 4, line 6. Ratcliff also teaches a composition (ClO_2) capable of breaking down the matrix components, and thereby help in the removal and prevention of dental plaque. Col. 4, lines 10-23. However, Ratcliff neither teaches nor suggests the use of krill derived enzymes to treat or prevent bacterial agglutination.

Hellgren teaches that krill, esp. Antarctic krill from the genus Euphausia, comprise of a number of different enzymes, including proteinases, peptidases, lipases, phosopholipases, and carbohydrate degrading enzymes. Col. 1 (lines 47-63) and col. 3. The reference indicates that these enzymes have molecular weights of between 51-80 and 20-40 kD. Column 4. The reference also teaches that composition comprising these enzymes is usable to remove biological contaminant from living or dead tissue. Col. 4, lines 3-23. Among the materials for which the composition is suggested as being useful for cleaning are teeth. Col. 1, line 31. This reference therefore suggests that a composition comprising krill derived enzymes may be used for the cleaning of teeth, and more particular for the removal of biological contaminants from teeth. However, the reference does not teach or suggest that the composition may be used to treat or remove dental plaque.

Karlstam teaches a krill derived enzyme that is usable to degrade a particular glycosaminoglycan. Abstract, and page 2. See also, On-Line Medical Dictionary, CancerWEB 1997-2002 (definition for glycosaminoglycan, and indication that glucosaminoglycan is another word for the same type of molecule- cited in parent application). The patent also teaches that the enzyme may be used in a number a therapeutic treatments. However, the application does not teach the use of the enzyme to degrade plaque.

One of ordinary skill in the art would know from the combination of Karlstam and Hellgren that enzymes derived from Krill has many therapeutic uses including both the cleaning of teach, and the use in therapeutic treatments. The references also tell one of ordinary skill in the art that compositions comprising these enzymes may be used to clean teeth, and to remove biological contaminant from the same. Hellgren also describes a method of use that includes repeated contact of the contaminant to be cleaned with the composition. Both Karlstam and Hellgren identify the enzymes as enzymes capable of degrading the components of the bacterial agglutination matrix taught by Ratcliff. Further, as these enzymes are capable of degrading the same components that are taught by Ratcliff as being targeted by the composition Ratcliff used to degrade plaque, one of ordinary skill in the art would have both been motivated to use, and had a reasonable expectation of success in the use of the krill enzymes to target dental plaque. As dental plaque may also be considered a biological contaminant and it is on teeth, the combination of Hellgren and Ratcliff clearly provide additional motivation to those of ordinary skill in the art to use the composition of Hellgren to remove dental plaque.

Double Patenting

14. Applicant is advised that should claim 144 be found allowable, claims 146 and 147 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In addition, claims 152, 153, 157, and 158 describe inherent features of the multifunctional enzyme of claim 151, and therefore read on the same invention as that claim.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one

claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the present case, claim 144 requires the presence of three enzyme activities. Claims 146 and 147, respectively, purport to further limit claim 144 to embodiments wherein "at least three" or "all of said proteolytic activities." As claim 144 already requires the presence of each of the three indicated activities (i.e. two endo-pepsidase activities and an exo-pepsidase activity), the requirements of claim 146 and 147 of at least 3 or of each of the described activities fails to add any additional limitations to the claim. Thus, claims 146 and 147 read on the same invention as claim 144.

Conclusion

15. No claims are allowed.

16. This is a continuation of applicant's earlier Application No. 09/549642. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648

Notice to Comply	Application No. 10/750184	Applicant(s) FRANKLIN, RICHARD	
	Examiner Zachariah Lucas	Art Unit 1648	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-0731 or (571) 272-0951
For CRF Submission Help, call (571) 272-2510
PatentIn Software Program Support
Technical Assistance.1-866-217-9197 or 703-305-3028 or 571-272-6845
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